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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,615	10/29/2003	Kenneth E. Trueba	10010217-1	9627

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HEWLETT-PACKARD COMPANY  
 Intellectual Property Administration  
 P. O. Box 272400  
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EXAMINER

MENDOZA, MICHAEL G

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/697,615	<b>Applicant(s)</b> TRUEBA, KENNETH E. <i>CA</i>	
	<b>Examiner</b> Michael G. Mendoza	<b>Art Unit</b> 3731	

-- **Th MAILING DATE of this communication app ars on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2003.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-30 and 32-57 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-30 and 32-57 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 29 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/29/03.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "32" has been used to designate both "main body", "separate body" and "applicator body". A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "30" has been used to designate both "applicator" and "dispenser". A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Specification***

3. The disclosure is objected to because of the following informalities: See drawing objections.

Appropriate correction is required.

### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-30 and 32-48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6684880. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claim is merely broader than the patent claim. The structural limitations set forth in claims 1-48 of the instant application are also claimed in the patent, e.g., an applicator for delivering a bioactive compositions, comprising: an inkjet dispenser comprising an orifice; a main body; a replaceable fluid reservoir; and a body orifice spacer.

***Claim Rejections - 35 USC § 112***

6. Claims 1-18 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. In claim 1, the applicant is required to clarify to what the claim is intended to be drawn to, i.e., either the applicator alone or the combination of the applicator and the bioactive composition. The applicant sets for the combination of the applicator and the bioactive composition when describing composition of the size of the bioactive droplets, which is inconsistent with the preamble, that sets for the subcombination of the bioactive composition. Applicant is required to make the language of the claims

consistent with the intent of the claims. It should also be noted that in considering the claims on the merits, the examiner will consider the claims as drawn to the combination.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-7, 10-16, 32-36, 43-48, 50-53, 56, and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Ivri et al. 6014970.

10. Ivri et al. teaches a pulmonary inhaler for delivering a bioactive composition, comprising; a piezoelectric droplet jet dispenser comprising a orifice for ejection of droplets; wherein the droplets are sized for respiratory inhalation for delivery to bronchial airways and a main body; a replaceable fluid reservoir; and a tubular curved mouthpiece external to the main body for partial insertion into a mouth of a human; wherein the mouthpiece changes a delivery direction (see figures); further comprising a programmable microprocessor (col. 12, lines 58-61).

11. Claims 19-21, 23-25, and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Makiej, Jr. 5002048.

12. Makiej, Jr. teaches an inhaler for delivering a bioactive composition, comprising: a jet dispenser comprising plural fluid ejection heads comprising dispenser orifices; multiple container holding different bioactive compositions; and a mouthpiece defining a

delivery pathway substantially transverse the inhaler and dimensioned for at least partial insertion into a mouth of a human (see figures).

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ivri et al. in view of Makiej, Jr.

15. Ivri et al. teaches the inhaler as claimed in claim 1. It should be noted that Ivri et al. fails to teach multiple replaceable fluid reservoirs; wherein the reservoirs hold and deliver two or more bioactive compositions.

16. Makiej, Jr. teaches a common inhaler comprising multiple replaceable fluid reservoirs for administering medication from multiple aerosol containers (col. 1, lines 52-54). Therefore it would have been obvious to one of ordinary skill in the art to modify the inhaler of Ivri et al. to include the fluid reservoirs of Makiej, Jr. to provide an inhalation device that facilitates administration of complementary medications (col. 1, lines 58-60).

17. Claims 17, 18, 37-42, 54, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ivri et al. in view of McKinnon et al. 6190326.

18. Ivri et al. teaches the inhaler as claimed in claim 15. It should be noted that Ivri et al. fails to teach wherein the controller is programmable from a remote computer and the controller is programmable from a keypad mounted on an external surface.

19. McKinnon et al. teaches a common controller for accurately collecting information about a patient's respirator condition (col. 1, lines 41-43). Therefore it would have been obvious to one of ordinary skill in the art to modify the controller of Ivri et al. to include the remote computer 18 and keypad 52 of McKinnon et al. to allow entry of the specifics of a treatment plan by the a physician (col. 5, lines 26-28).

20. Claims 22 and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makiej, Jr. in view of Ivri et al.

21. Makiej, Jr. teaches the applicator according to claim 19. It should be noted that Makiej, Jr. fails to teach wherein is a piezoelectric droplet jet dispenser.

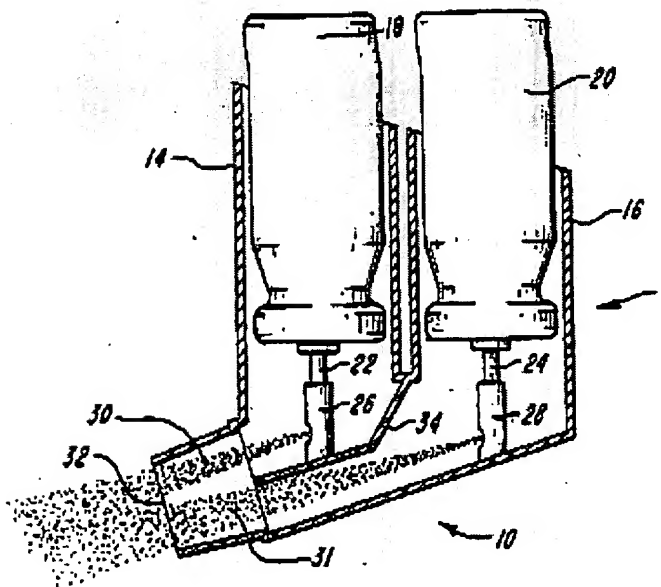
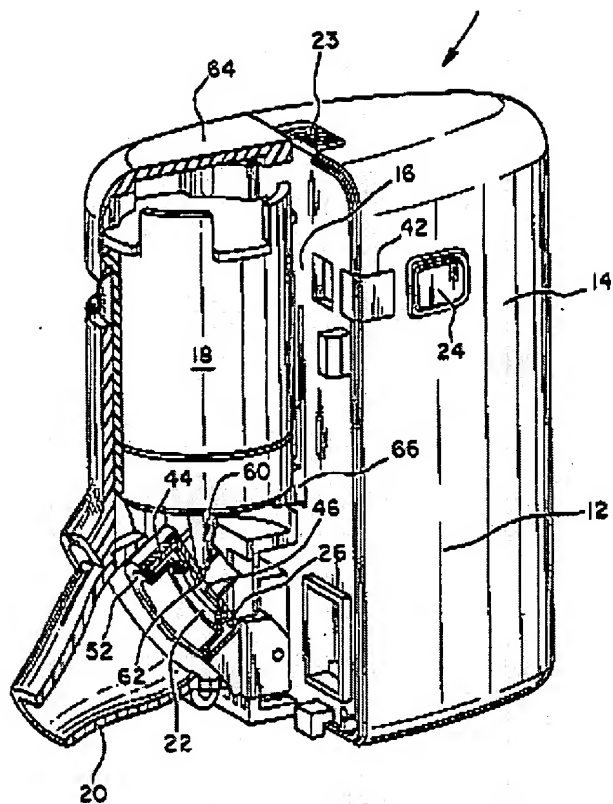
22. Ivri et al. teaches a common apparatus with a piezoelectric droplet jet dispenser for atomization of the liquid to be delivered. Therefore it would have been obvious to one of ordinary skill in the art to modify the apparatus of Makiej, Jr. to include the piezoelectric droplet jet dispenser of Ivri et al. to produce a high flow of droplets in a narrow size distribution for delivery of drugs to the lungs (col. 2, lines 29-40; 970).

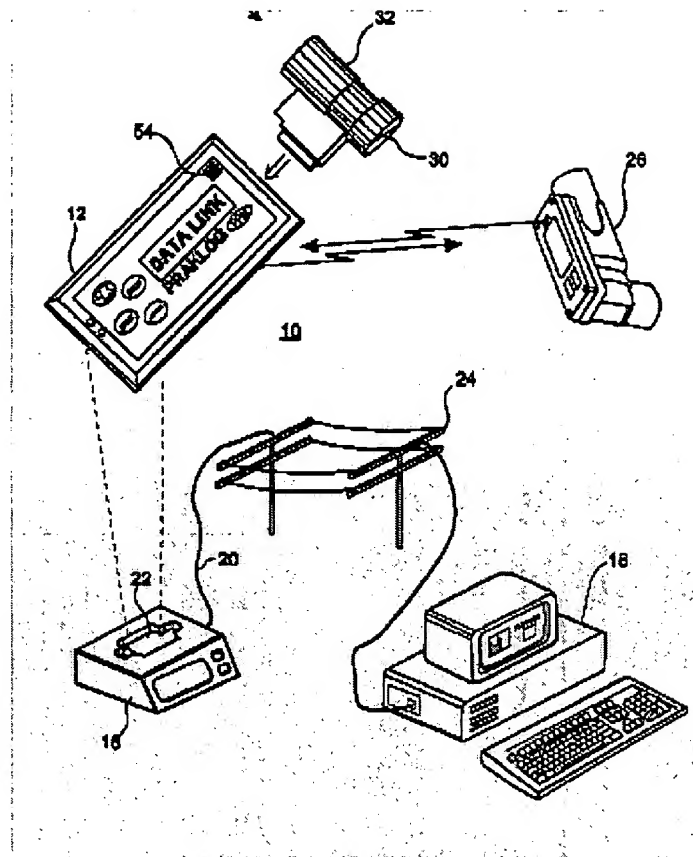
23. As to claims 26, 27, and 30, Makiej/Ivri teaches the applicator of claim 19 comprising a microprocessor; wherein the microprocessor is programmable to deliver bioactive compositions from the applicator in response to clinical or physical information (col. 12, lines 58-61; 970).

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24. As to claim 28 and 29, Makiej/Ivri teaches a controller. Applicant has not positively claimed a program associated with the controller, computer, microprocessor to perform the function as recited. Therefore, the controller of Makiej/Ivri is capable or programmable to perform the functional limitation associated with the controller as recited in claims 28 and 29.







### ***Contacts***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Glenn Dawson can be reached on (571) 272-4694. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MM

  
GLENN K. DAWSON  
PRIMARY EXAMINER